Risk Assessment Approach for Adults and Children in the Libby Community

The human health risk assessments for the Libby Asbestos Superfund Site are drafted following the EPA Guidance (1989, 2008a, 2009). The following sections provide a general outline for the conduct of human health risk assessments for adults and children at the Libby Site.

Libby Risk Assessment Process

Risk assessment is a process for evaluating and documenting public health and ecological threats. EPA provides general guidance for conducting and reporting the results of risk assessments (EPA, 1989) and additional guidance specific for asbestos contaminated Superfund sites is provided by EPA (2008a). The EPA 2008a guidance recommends activity-based sampling (ABS) for breathing zone air sampling. The risk assessment process consists of four major steps: 1) data collection and evaluation; 2) exposure assessment; 3) toxicity assessment; and 4) risk characterization. A brief description of each of the steps follows.

Data Collection and Evaluation

The data collection and evaluation step includes development of a sampling and analysis plan, implementation of the sampling and analysis plan in a site investigation, site characterization, analysis of the data, and selection of chemicals of concern. The sampling and analysis plan provides guidance for the collection and analysis of environmental data at the Libby site. Soil and air are the two major environmental media sampled at Libby. Activity-based sampling (ABS) is used to provide the most reliable estimation of soil contamination by evaluating the soil-to-air pathway. The site characterization uses these data to describe the physical and chemical attributes of the site and the location of contamination. The data analysis portion of the process evaluates the analytical data from the field sampling and defines the concentration of contaminants identified at the site. Based on the site characterization and data analysis, chemicals of potential concern are determined for further evaluation in the risk assessment. For the Libby Asbestos Superfund Site, the chief chemical of concern is Libby Amphibole. There are, however, additional chemicals of concern for OU3, including metals and some organics.

Exposure Assessment

The exposure assessment evaluates how potential human receptors can contact the environmental media and contaminants. An exposure pathway consists of a source of contaminant and release mechanism, a transport mechanism/media, a point of human contact, and an exposure route. Only completed exposure pathways are evaluated. Once an exposure route is completed, exposures are quantified by calculating a time-weighted

average exposure concentration. This process involves estimating daily intake, frequency of exposure, duration of exposure, and concentration of constituent in the media. The time-weighted dose is prorated over a theoretical body weight and life time average. Based on site-specific evaluation, the inhalation exposure pathway is the major route of human exposure in Libby. For Libby, the exposure concentration is calculated and reported in structures per cubic centimeter of air (s/cc) reported as Phase Contrast Microscope Equivalents (PCME).

Toxicity Assessment

The toxicity assessment evaluates and summarizes the toxicity data available for the chemicals of concern being evaluated in the risk assessment. There are two major classifications of toxicants that are evaluated: non-cancer, threshold toxicants, and cancer-causing toxicants. Currently, there are no Libby Amphibole-specific toxicity factors for assessing non-cancer endpoints or cancer endpoints. Non-cancer toxicity factors (reference dose (RfD) and reference concentration (RfC)) are used in calculating a hazard index (a measure of non-cancer toxicity). Cancer toxicity factors (slope factors (SF) and Inhalation Unit Risk factors (IUR)) are used to estimate theoretical excess cancer risks which are probabilities. The source of toxicity values may originate with animal, human, or a combination of animal and human toxicity data. The currently available toxicity value for asbestos is the IRIS Inhalation Unit Risk (IUR) established in 1986 (EPA, 1986), which is based on studies of the health effects of chrysotile and tremolite asbestos. This value has been applied in Libby to develop interim cleanup decisions while the Libby Amphibole-specific toxicity values are being developed. The IRIS Asbestos IUR is based on human, occupational epidemiological investigations with an endpoint of mortality and morbidity for the combination of lung cancer and mesothelioma. There are no non-cancer toxicity values for any form of asbestos that can be used to assess the potential risks for developing non-cancer diseases manifested in the Libby population (asbestosis, pleural diseases and abnormalities, non-malignant respiratory disease, auto immune and cardiovascular diseases). EPA is sponsoring research to develop Libby Amphibole-specific toxicity factors.

Risk Characterization

The risk characterization utilizes information from the data collection and evaluation, exposure assessment, and toxicity assessment to estimate risks to human receptors. Two types of risks are quantified: threshold non-cancer effects; and theoretical excess cancer risk.

<u>Non-Cancer Risk</u>

The Hazard Index is the term used to describe the non-cancer, threshold risk and is calculated as follows:

$$Hazard\ Index = [Average\ daily\ dose]/[Acceptable\ dose]$$

where   Average daily dose = (PCME s/cc-yr)
               Acceptable dose = (Reference Concentration, PCME s/cc-yr)

The hazard index is a ratio of the calculated dose divided by an acceptable dose. When the ratio is < 1, there is no concern that threshold effects will be expressed. When the ratio is > 1, there is a concern that threshold effects will be expressed. The child receptor (due to the size, exposure rate, and lower body mass) usually is the most sensitive population to non-cancer effects. Since we lack a reference concentration for Libby Amphibole (or any other form of asbestos), a hazard index cannot be calculated for exposure to Libby Amphibole at the Libby site. This represents a gap in our ability to fully assess risk at the Libby site.

Cancer Risk

The cancer risk generally is expressed as a theoretical excess risk (a probability) of developing cancer over a lifetime exposure. In the case of asbestos, EPA has provided specific guidance for estimating theoretical excess lifetime cancer risk in the Framework for Investigating Asbestos-Contaminated Superfund Sites (EPA, 2008 a) and the Risk Assessment Guidance for Superfund, RAGs Part F, Inhalation Pathway Analysis (EPA, 2009). This guidance calls for cancer risk quantification using the following equation:

$$ELCR = [EPC] \, x \, [TWF] \, x \, [IUR]$$

where: ELCR = Excess Lifetime Cancer risk
                EPC = Exposure Point Concentration (the concentration of asbestos
                         fibers in air (s/cc) for the specific activity being assessed

                IUR = Inhalation Unit Risk (s/cc)-1

The framework was developed to assess theoretical excess cancer risks for less than lifetime exposures, thereby allowing for potential estimation of risk(s) to children, young adults, and adults. This is important since a reference concentration is not available and risk to young receptors could not otherwise be estimated. Hence, risk estimations from asbestos exposure are based solely on prediction of theoretical excess cancer risk for inhalation exposures.

Under the CERCLA process, cumulative risk may need to be estimated for an individual exposed to several environments or exposure scenarios (e.g., playing in the dirt, moving a lawn, athletic activities, etc.). Cumulative excess lifetime asbestos cancer risk can be estimated as follows:

          where $ELCR_c$ is the cumulative excess cancer risk attributed to multiple
          environments or multiple scenarios over the course of the exposure duration of the
          individual.

The risk characterization portion of the risk assessment usually contains an uncertainty section which discusses the strengths and weaknesses of the risk assessment. Topics such as exposure assumptions, data gaps, data quality, fate and transport modeling, toxicity factors, and mode of action of contaminants can influence the risk evaluation. The uncertainty section evaluates these factors qualitatively and sometimes quantitatively.

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